Physical Activity Monitoring in Patients with Peripheral Arterial Disease: Validation of an Activity Monitor

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WHAT THIS PAPER ADDS

The aim of the study was to validate a tri-axial activity monitor to measure daily activities and walking steps (physical activity) in patients with intermittent claudication. A clear call in vascular research for alternative tests to determine walking capacity or walking behaviour in patients with peripheral arterial disease (PAD) has been made. This study validated an activity monitor to measure these types of outcome variables, which may offer a valuable contribution to the research armamentarium of PAD and could therefore support future PAD research.

Objectives: The daily life physical activity (PA) of patients with peripheral arterial disease (PAD) may be severely hampered by intermittent claudication (IC). From a therapeutic, as well as research, point of view, it may be more relevant to determine improvement in PA as an outcome measure in IC. The aim of this study was to validate daily activities using a novel type of tri-axial accelerometer (Dynaport MoveMonitor) in patients with IC.
Methods: Patients with IC were studied during a hospital visit. Standard activities (locomotion, lying, sitting, standing, shuffling, number of steps and "not worn" detection) were video recorded and compared with activities scored by the MoveMonitor. Inter-rater reliability (expressed in intraclass correlation coefficients [ICC]), sensitivity, specificity, and positive predictive values (PPV) were calculated for each activity.
Results: Twenty-eight hours of video observation were analysed ($n = 21$). Our video annotation method (the gold standard method) appeared to be accurate for most postures (ICC > 0.97), except for shuffling (ICC $= 0.38$). The MoveMonitor showed a high sensitivity (>86%), specificity (>91%), and PPV (>88%) for locomotion, lying, sitting, and "not worn" detection. Moderate accuracy was found for standing (46%), while shuffling appeared to be undetectable (18%). A strong correlation was found between video recordings and the MoveMonitor with regard to the calculation of the "number of steps" (ICC $= 0.90$).
Conclusions: The MoveMonitor provides accurate information on a diverse set of postures, daily activities, and number of steps in IC patients. However, the detection of low amplitude movements, such as shuffling and "sitting to standing" transfers, is a matter of concern. This tool is useful in assessing the role of PA as a novel, clinically relevant outcome parameter in IC.

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INTRODUCTION

In daily life, patients with symptomatic peripheral arterial disease (PAD) may be severely limited owing to symptoms of intermittent claudication (IC). Disease severity and the effect of treatment modalities are often assessed by outcome measures such as maximum and pain-free walking distance. However, a large discrepancy and variability has been reported between walking ability and claudication walking distances as measured on a treadmill, suggesting that treadmill assessments may not be representative of daily life walking ability.[1–3] Assessment of IC using patient-reported outcomes is subjective and insensitive, and a poorly reproducible tool for determining the severity of symptoms.[4–6] Objective clinical measurements such as Doppler ultrasonography and angiography only provide information on vessel patency and lesion severity. These imaging techniques are registered under standardised

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conditions and do not take the patients' coherent daily ambulatory limitations into account.

A clear call has been made for alternative tests to determine walking capacity over a prolonged period of time.[1,2] Moreover, despite the fact that patients with IC have an increased risk of cardiovascular or cerebrovascular events,[7] current treatment for PAD is mainly focused on the limitation of walking distance. However, an increased walking capacity does not automatically imply a change in a patient's exercise behaviour. From a therapeutic, as well as a research, point of view, it may be more relevant to determine physical activity (PA) as an outcome measure for treatment modalities of IC. Improved levels of PA might be indicative of an increased exercise behaviour resulting in a reduction in the risk of cardiovascular events and an improvement in quality of life in the long term.[8,9] In the past, habitual PA was frequently ascertained using questionnaires or diaries, but patients are known to report inaccurately, and results tend to be biased owing to socially desirable answers.[4–6] Therefore, it seems necessary to obtain an objective measure of a patient's PA over a prolonged period of time.

Nowadays, PA levels can be measured with activity monitors. Tri-axial accelerometers measure acceleration in three dimensions that can be converted to intensities and metabolic equivalents (METs), which enables quantification of overall PA. The Dynaport (DP) MoveMonitor (McRoberts, The Hague, the Netherlands) is such an activity monitor and is easily applicable in a daily life setting and optimised for clinical research assessments. The DP has previously been validated in an elderly population,[10] in Parkinson disease,[11,12] and patients with chronic obstructive pulmonary disease (COPD).[13–15] To our knowledge, studies validating the DP in detecting daily activities in a PAD population have not previously been reported. However, symptoms of IC may significantly influence the outcomes of the DP owing to altered walking patterns which may have an impact on the detection of gait and postures.[16–18] Furthermore, all previous studies were performed in a laboratory setting with patients walking a specific trajectory.[10–13] Moreover, the number of observation hours has been rather limited and obtained from small groups.[10,11,13,15] One study excluded patients with walking impairments and two other studies used outdated accelerometer technology.[13–15] Overall, most studies have suffered from substantial methodological shortcomings when using the DP for assessing daily life ambulatory activities in patients with walking impairment due to IC.

The aim of this study was to validate the DP MoveMonitor in symptomatic patients with IC in a near-real life setting. If valid, the accelerometer can be used for the assessment of PA as a potential outcome measure in these populations.

METHODS

Recruitment

Patients with IC (PAD stage 2–3 according to the Rutherford classification) and visiting the vascular outpatient clinic of Catharina Hospital between August and November 2012 were eligible for this study. The study was conducted with the approval of the local medical ethics committee.

Inclusion criteria

The inclusion criteria were >3 months of symptoms of IC, and an ankle-brachial index (ABI) <0.9 at rest or a fall in systolic ankle pressure by >20% after treadmill testing. A treadmill protocol with a fixed inclination of 8% at 3.2 km/h for a maximum of 5 minutes was used.

Exclusion criteria

Patients with walking difficulties other than those due to IC were excluded (e.g., prior amputation, severe arthritis, COPD Global Initiative for Chronic Obstructive Lung Disease score 3–4, congestive heart failure [>New York Heart Association class II]), as was the use of walking aids. Patients with recent (<12 months) vascular surgical intervention prior to the study were also excluded, as were patients who were unable to understand all the specifics of the study protocol or that had insufficient knowledge of the Dutch language.

Video observation and activity monitoring

Patients' medical and surgical histories were obtained, followed by physical examination and a check of inclusion and exclusion criteria. After signing informed consent, a DP attached to a neoprene belt was strapped around the patient's waist at the level of the mid-lower back (Fig. 1). The patient's hospital visit (e.g., waiting room, doctor's visit, vascular laboratory assessments, treadmill testing, etc.) was then continuously recorded on video (GZ-HM335BE; JVC, Yokohama, Japan). Subsequently, patients were asked to walk around the hospital's car parking lot, as abnormal walking due to IC could possibly occur during this effort. Patients were instructed to act and move as they normally would. Patients were filmed anonymously. Two observers were randomly assigned to perform all video recordings.

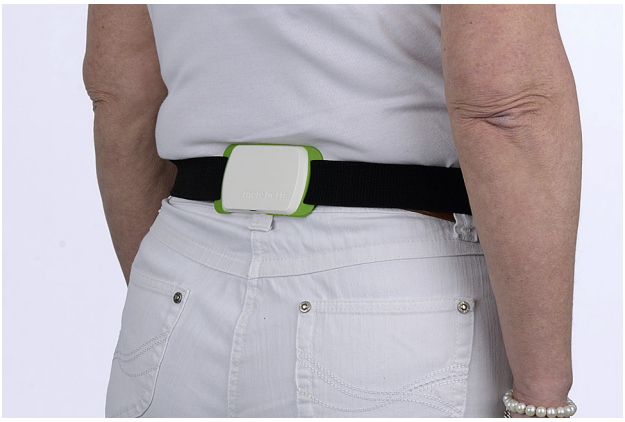

Figure 1. A patient wearing the DynaPort MoveMonitor (McRoberts, The Hague, the Netherlands).

Video recording of the activities was considered as the "gold standard".

Categorising movements by video

Table 1 depicts seven standard categories associated with daily activities, including lying, sitting, standing, shuffling, locomotion, (device) "not worn", and "activity not recorded" (private actions, such as visits to the restroom). The specifics of each category and transitions between the seven categories were described in detail. A concise description of categorical and transitional activities formed the basis for a subsequent evaluation of all video recordings. All recorded activities were scored in time per activity (in seconds) using annotation software (ELAN 4.4.0; Max Planck Institute for Psycholinguistics, Nijmegen, the Netherlands) and exported as Excel (Microsoft, Redmond, WA, USA) files. Additionally, the number of steps of all walking activities per patient was counted. All video recordings were scored in duplicate by two observers, allowing for verification of inter-rater reliability (IRR).

Table 1. Annotation protocol.

Category	Interpretation
Lying	Lying
	From standing to lying: starting from the sitting position
	sitting with straight legs
Sitting	Sitting
	From standing to sitting: starting from flexion of the hip
	From lying to standing when subject is sitting >5 s during the transition
	Trunk movements during sitting
	Dressing and undressing during sitting
Standing	Standing
	From sitting to standing: starting from extension of the hip
	A pause during walking >5 s
	Shuffling <5 s before a transition from standing to lying/sitting
	Dressing and undressing during standing
Locomotion	Walking
	Walking upstairs
	A pause during walking <5 s
	Shuffling <5 s before a transition from walking to lying/sitting
	Shuffling <5 s before a transition from standing to walking
Shuffling	Shuffling
	Shuffling >5 s between two other activities
	Shuffling >5 s before a transition from standing/walking to lying/sitting
Device not worn	The time period in which the DP is picked up from a table and attached to the patient
	The time period in which the patient is not wearing the DP during a video recorded measurement
Not recorded	The time period in which the DP already is measuring data, but video recording is not yet started
	The patient is wearing the DP, but is not verified by video recording, e.g., undressing or going to the toilet

Note. DP = DynaPort MoveMonitor (McRoberts, The Hague, the Netherlands).

DP

We chose to use the tri-axial DP accelerometer (84 × 50 × 8 mm, 70 g) to monitor activities. Compared with other activity monitors, the DP showed high correlations between indirect calorimetry and generated MET output, whereas walking speed was correctly measured in a population with COPD.[19] The device consists of a tri-orthogonal orientated piezo-capacitive acceleration sensor, a rechargeable battery, and removable secure digital card to store the acceleration data. A DP stores digital data for a maximum of 7 days. The raw acceleration data lend themselves to a pattern recognition approach using logical algorithms (MoveMonitor analysis software, version 2.6) for the classification of postures (lying, sitting, and standing) and motions (locomotion and shuffling). The detection algorithm consists of five major parts, as described previously.[11,12] The first step is gait period detection based on an intensity threshold. These potential gait periods are scanned using frequency analysis and a validated step detection method, resulting in three categories: walking, active (but not walking), and static periods. Second, transition detection is performed to identify upward or downward transitions. The result is the identification of either up (standing) or down (lying or sitting). Subsequently, angle calculation based on sensor tilt is used to determine whether the down part of this vector can be identified as lying (<30°) or sitting. Next, shuffling separation divides the active (not walking) parts into two categories: shuffling and transitions. Shuffling is defined as all movement from A to B that is not walking. Thus, if the number of steps is fewer than three, or the intensity and direction of the motion do not comply with the characteristics of walking, the movements are classified as shuffling. The results of the software analysis were returned in comma separated value files. The reports listed six of the described activities per second (Table 1), except for the "activity not recorded" category. Data obtained from the DP were synchronised with data generated by video recording (ELAN 4.4.0).

Data analysis

The first analysis of the data was aimed at determining the IRR of video recording, which is considered to be the gold standard. The duration of activity (in 0.1 seconds) per category was summed for each patient. To obtain an impression of the distribution, these values were analysed for skewness and kurtosis. In the case of normally distributed data, the IRR of video recording was determined by comparing the total duration per activity between both

observations using intraclass correlation coefficients (ICC) with a two-way mixed model and absolute agreement.

The aim of the second analysis was to validate the DP using two types of analyses. Transformation in an "activity per second" format was required for annotation files. For this purpose, a computer program was developed (MATLAB 7.14; MathWorks, Natick, MA, USA). The software converted the annotated duration of activities into an "activity per second" format. Activities defined by the DP and video recordings were than compared by matching each activity per second for the six overlapping categories (except for the "not recorded" category). The agreement between the DP and the gold standard was calculated per subject by adding up the duration of when the activity codes matched, and expressed as a percentage of the total duration that an activity was observed on video. Non-agreement percentages per patient were defined as:

> Total duration that the video observation and the DP corresponded at the same moment for the not "not activity category"/total duration that the "not activity category" was observed on video $\times 100\%$

Sensitivity, specificity, and predictive values were calculated by taking the mean agreement or non-agreement values for each activity category, as suggested by Dijkstra et al.[11] The second determination of the validity of the DP was using ICCs for step count. Gait characteristics as observed on video were again considered as the "gold standard". Steps performed on the treadmill (to obtain ABIs) were analysed separately from walking during a patient's hospital visit. "Not recorded" periods of >5 seconds were excluded from analysis. Outliers of agreement were estimated per activity category and defined as four times the SD of agreement. ICC was considered strong if ≥ 0.7, moderate between 0.3 and 0.7, and weak ≤ 0.3. *p*-Values $<.05$ were considered to be statistically significant. Statistical analysis was performed using SPSS Statistics (MAC OS X version 20.0; IBM, Armonk, NY, USA).

RESULTS

Twenty-seven patients were eligible, and all consented to the study. However, the data of six patients were excluded for reasons listed in Fig. 2. The characteristics of the remaining 21 patients are shown in Table 2. Bilateral IC symptoms were observed in 71% of the patients. More than half (13/21, 62%) had undergone peripheral vascular surgery, but still reported symptoms of IC. A total of 27.9 hours of video film was obtained and analysed. The mean video time was 83 minutes/patient (range 48–110 minutes).

IRR of video observations

IRR data were normally distributed. IRR between both video observers was excellent for most activity categories (ICC = 1.00 for lying, sitting and walking; ICC = 0.98 for standing; $p < .005$). Moreover, the ICCs for "device not worn" and "not recorded" detections were also excellent (1.00 and 0.99, respectively; $p < .005$). However, the ICC (0.38) for shuffling was poor.

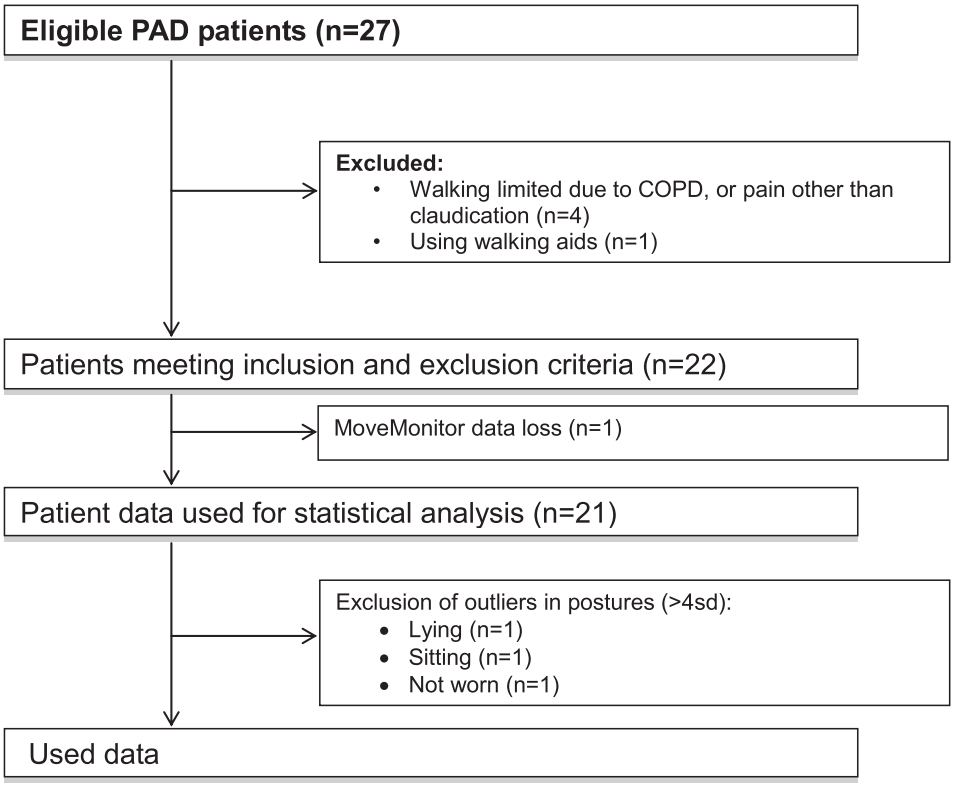

Figure 2. Flowchart of study population allowing validation of the DynaPort MoveMonitor (McRoberts, The Hague, the Netherlands). *Note*. PAOD = peripheral arterial occlusive disease; COPD = chronic obstructive pulmonary disease.

Table 2. Patient demographics.

	Population analysed ($n = 21$)
Sex (% male)	62
Age (years ± SD)	67 ± 10
BMI (kg/m^2 ± SD)	26 ± 4
Affected side (%)	
Left	24
Right	5
Both	71
ABI	
Rest, worst leg (mean ± SD)	0.70 ± 0.21
Rest, best leg (mean ± SD)	0.92 ± 0.17
Postexercise, worst leg (mean ± SD)	0.49 ± 0.28
Postexercise, best leg (mean ± SD)	0.79 ± 0.28
Cardiovascular medical history (%)	
PTA	35
Leg surgery	25
CABG/PCI	40
Other	25
Comorbidity (%)	
COPD	29
Arthritis	14

Note. BMI = body mass index; ABI = ankle-brachial index; PTA = percutaneous transluminal angioplasty; CABG = coronary artery bypass grafting; PCI = percutaneous coronary intervention; COPD = chronic obstructive pulmonary disease.

Validity of the DP

Mean duration (±SD) of the postures standing, locomotion, lying, and sitting per patient were 8.7 (±6.1), 15.8 (±5.9), 15.2 (±6.9), and 35.3 (±17.1) minutes, respectively. The total duration of these four postures ranged from 183 to 707 minutes (Table 3). In contrast, shuffling was measured for a mere 5 minutes (24 ± 18 seconds) and occurred in 12 patients only. The "device not worn" category was registered in just seven participants, with a total measured time of 160 minutes (22.9 ± 9.8 minutes). Just 22 seconds (<0.1% of total time registered) were labelled as a "not recorded" event, leading to removal from further analysis. In total, five of the 126 obtained activities (3.9%) were defined as outliers (more than four times SD of agreement) and were detected in the categories locomotion, sitting and "not worn" (see Table 5).

Table 4. Specificity and positive predictive values (PPVs) of the DynaPort MoveMonitor (McRoberts, The Hague, the Netherlands).

Activity	Specificity (%)	PPV (%)
Locomotion	99.0	94.9
Lying	98.6	94.1
Shuffling	98.7	3.7
Standing	93.9	47.8
Sitting	91.4	88.3
Not worn	99.6	95.4

Note. Video observation data are used as the gold standard.

The agreement between video observation and DP data of observed activities is given in Table 3. High levels of sensitivity were found for locomotion (86%), lying (97%), sitting (91%), and "device not worn" (89%). High specificities and positive predictive values (PPVs) were also found with regard to these four categories (>88%; Table 4).

In contrast, the DP showed a low (46%) sensitivity value (Table 3). In reality "sitting" was performed in 37% of the remaining "for standing" time (Table 3). This poor agreement is likely owing to aberrant data obtained from 10 of the 21 patients. Eight of these 10 patients were actually sitting (instead of standing) in 50–75% of the videoed time. In the two other measurements, the patient was moving in 28% and 29% of the "standing" time, respectively. Video observations and DP data also showed a low agreement in the category of shuffling (18%; Table 3), although a high specificity (99%) was found.

Data obtained during walks taken at a patient's hospital visit (mean number of steps 1,561 ± 675) and treadmill walking (mean number of steps 473 ± 155) were normally distributed and used for step analysis. The ICC of calculated steps between video observation and DP data was 0.90 (95% confidence interval [CI] 0.77–0.96, $p = .001$) and 0.84 for treadmill walking (95% CI 0.63–0.93). One patient performed 2,199 steps, while the DP detected just 908 steps. Analysis revealed that this patient wore the DP upside down. The data set of this patient was defined as an outlier and excluded from the activity analysis ("locomotion activity"; Table 5), but not for the step analysis.

Table 3. Agreement and non-agreement between video observation and DynaPort (DP) MoveMonitor (McRoberts, The Hague, the Netherlands) data per activity.

		Total video observation time (min)	Activity as categorized by the DynaPort					
			Locomotion[a]	Lying	Shuffling	Standing	Sitting[a]	Not worn[b]
Video observation	Locomotion	315	**86.1 ± 11.8**	0.5 ± 0.9	2.3 ± 1.6	8.8 ± 7.2	2.8 ± 4.6	0.0
	Lying	319	0.5 ± 0.7	**96.8 ± 3.9**	0.3 ± 0.4	0.4 ± 0.9	1.9 ± 2.7	0.0
	Shuffling	5	6.6 ± 7.0	0.0	**17.5 ± 13.8**	49.2 ± 24.5	26.7 ± 30.6	0.0
	Standing	183	5.3 ± 8.2	3.5 ± 4.3	5.9 ± 3.9	**46.2 ± 19.0**	37.1 ± 22.2	0.4 ± 1.9
	Sitting	707	0.3 ± 0.4	0.5 ± 0.8	0.4 ± 0.5	7.4 ± 11.8	**90.6 ± 12.3**	0.9 ± 3.9
	Not worn	160	0.0 ± 0.1	4.9 ± 3.6	0.2 ± 0.2	5.8 ± 10.1	0.2 ± 0.2	**88.7 ± 9.3**

Note. Values are presented in percentages (mean ± SD). Video observation data are used as the gold standard. Sensitivity values of activities categorized by the DP are depicted in bold.

[a] One outlier was excluded.

[b] Three outliers were excluded.

Table 5. Data of removed outliers per activity.

Observed activity (by video registration)	Total duration (s)	Activity as categorized by the DynaPort					
		Locomotion (% of time)	Lying (% of time)	Shuffling (% of time)	Standing (% of time)	Sitting (% of time)	Not worn (% of time)
Locomotion	1,346	**38.9**	0.2	5.4	35.7	19.4	0.0
Sitting	876	0.2	0.7	0.1	59.8	**39.1**	0.0
Not worn	1,875	0.0	98.7	0.3	0.5	0.4	**0.0**
Not worn	162	0.0	0.0	0.0	100	0.0	**0.0**
Not worn	469	0.0	1.9	1.3	95.1	1.7	**0.0**

Note. Agreement values per patient per activity are depicted in bold.

DISCUSSION

Symptoms of IC might influence activities of daily life. Moreover, IC may have profound consequences for exercise ability, behaviour, and levels of PA. Findings of this "real life" design study indicate that activities detected by the DP showed high sensitivity and specificity values for most activity categories except for "standing" and "shuffling".

Measuring IRR characteristics is an important step in the evaluation of a "gold standard" that is used to validate novel tools, such as the DP. Strong correlations concerning the IRR were found in six out of seven activity categories. In contrast, a poor IRR was found for shuffling (ICC = 0.38). High IRRs were previously found in a similar, but smaller, video study of five elderly patients (ICCs = 0.95, 0.78, 0.99, and 0.98 for walking, sitting, standing, and lying, respectively).[12] The poor ICC for shuffling is probably due to ambiguities in our annotation protocol and the DP data analysis method (Table 1). Furthermore, transitions per se were difficult to score using a "per second" time window analysis method, whereas the duration of a particular transition between activities is often a matter of seconds, a phenomenon that has also been reported previously.[11]

A poor sensitivity of 46% of the DP was found for "standing" (PPV 47.8). This is somewhat lower than other studies carried out with community-dwelling and Parkinson disease patients (80% and 81%, respectively).[10] Additionally, we found a large SD (19%) for the "standing" activity, which can be explained by 10 aberrant measurements. It is thought that the DP missed several transitions between sitting and standing, which may have considerably influenced outcomes, especially owing to increased durations of activities. The low PPV of shuffling (4%) is particularly striking, and induced by a low IRR and a difference between the annotation protocol and the algorithms that were used by the DP in allocating transitions to specific activities. According to our protocol, observers assessed transitions between activities as part of the previous activity; in contrast, the DP scored them as shuffling. Therefore, conclusions regarding shuffling cannot be drawn from this study. However, it should be appreciated that shuffling activities were only observed during a relatively short period (1% of the total time recorded). Therefore, the effect of shuffling on the overall performance of PA is very limited.

An overestimation of gait duration (11%) and underestimation of the number of steps (7%) in Parkinson disease patients has previously been reported.[12] However, these studies were performed in a laboratory setting with relatively short distances and just 236.8 minutes of video observation per study. Despite the fact that walking patterns are altered in patients with IC,[16–18] this study, which was executed under daily life conditions using prolonged video observation periods, demonstrated that the DP can accurately measure the number of steps in a population of patients with IC.

Studying PA levels and ambulatory activities in daily life may yield important information regarding quality of life, health status, or mortality in chronic diseases such as COPD and PAD/IC. There is increasing interest in understanding associations between sedentary activities and their impact on quality of life.[20–22] As a consequence, research interest may shift from focusing on the measurement of exercise capacity (maximal or pain-free walking distances) to determining daily activities over a prolonged period of time. Our study shows that the DP can correctly measure most types of ambulatory activities in daily life. Future research should aim to determine the value of PA as a novel outcome measurement in IC-related topics, such as in the comparison between IC treatment modalities.

Study limitations

Video observers and the DP scored shuffling differently. In retrospect, positional change would have been marked as shuffling. Furthermore, reference values of physiological or walking intensity parameters were not obtained, although the DP is capable of determining the intensity of periods of locomotion (movement intensity).[23] Therefore, a validation of energy expenditure values could not be made. Although movement intensity may be of importance in patients with IC, this study focused on validation of periods of activities rather than intensity. The assessment and effect of treatment strategies on PA and daily activities in patients with PAD should be the subject of future research.

Conclusion

A tri-axial Dynaport activity monitor provides accurate information on a diverse set of daily activities in patients with IC when compared with a video technique. However, the detection of low amplitude movements such as shuffling and "sitting to standing" transfers is a matter of concern. This tool is useful in assessing the role of PA as a novel, clinically relevant outcome parameter in IC.

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CONFLICT OF INTEREST

None.

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